REMARKS

Claims 5 and 18 have been cancelled, and new claims 19 and 20 added. Claims 1 -4, 9 – 11, and 15 – 17 have been amended. Upon entry of the amendments, claims 1 – 4 , 6 – 17, 19, and 20 remain pending in the application.

Support for the amendments is found in the specification and claims as originally filed. Because the claims contain no new matter, entry is proper and respectfully solicited.

The specification has been amended at page 8 to correct an oversight of the drafter who unintentionally left in correction remarks. The amendment clarifies the correction remark. Support for the amendment is found for example, in the table immediately above the amendment where it states that the amount of Eudragit® L30D55 is 13.30 based on solids.

w/d but claim 1 still says "final coating"

Rejection Under 35 U.S.C. § 112

Claims 1, 4, and 9 - 11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant's regard as the invention. Applicants believe the amended claims are definite and accordingly traverse the rejection as applied to the amended claims and request reconsideration.

Applicants have deleted the alleged indefinite term of "functional coating" in claims 1, 9, and 11, and replaced it with the term "coating". While Applicant believes the word "functional" did not render the claim indefinite, the amendment is being offered to expedite prosecution. It is to be noted that the amendment actually broadens the

scope of the claim. In a similar fashion, the "sustained release" language in the preamble objected to by the Examiner has been deleted. The preamble is now drawn to a "tablet composition". For these reasons, Applicant respectfully requests that the rejection be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 1 – 18 stand rejected under 35 U.S.C. § 103 as obvious in light of Morella et al., U.S. patent 5,378,474 (the Morella reference). Applicant respectfully traverses the rejection as applied to the amended claims and requests reconsideration.

To sustain a rejection of claims under § 103 over a single reference, there must be a motivation to modify what the reference discloses to arrive at the subject matter of the claims. A modification is not obvious unless there is a teaching of the desirability of such a modification. Where the reference teaches away from making the modification, there is lack of motivation for the modification.

The claims recite a coating composition that has a polymer component and a non-polymer component. The polymer component consists essentially of a polymer soluble above pH 5.5 and an optional amount of polyethylene glycol. "Surprisingly, the coating of the invention presents the unique feature of preventing the whole dosage form from being influenced by food intake." Page 4, lines 1 – 4. The transitional language in the amended claims excludes compositions having significant amounts of a third polymer that would materially affect the novel characteristics of the invention.

The Morella reference teaches away from modifying its disclosure to arrive at the subject matter of the amended claims. It requires a very specific coating to impart the desired sustained release effect, namely a combination of an insoluble matrix polymer, an enteric polymer, and an acid soluble polymer. See, e.g., column 8, lines 38 – 45. The Morella reference continues:

> It has been found necessary in order to achieve a slow rate of release at acidic pH of pH dependent or independent drugs, and faster relatively constant rate of release over an extended period of time to include the above three components in the hybrid core coating composition.

Column 8, ll. 46 – 51 (emphasis added). The Morella clearly teaches that its coating must have three polymeric components.

In light of the above discussion, Applicant respectfully submits that the amended claims are patentable over the disclosure of the Morella reference. Accordingly, Applicant respectfully requests that the rejections be withdrawn.

CONCLUSION

For the above reasons, Applicant believes that claims 1 – 4 , 6 – 17, 19, and 20 are in an allowable condition and respectfully request an early notice of such allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issue.

Respectfully submitted,

Dated: Nov 19, 2001

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ATTACHMENT FOR SPECIFICATION AMENDMENTS

The following is a marked up version of each replacement paragraph and/or section of the specification in which underlines indicates insertions and brackets indicate deletions.

Eudragit® L30D55 is methacrylic copolymer available from Rohm. The 13.30 value represents the weight of the solids and not the weight of the dispersion [IS THE VALUE 13.30 THE WEIGHT OF THE DISPERSION OR THE WEIGHT OF THE SOLIDS Solids].

ATTACHMENT FOR CLAIM AMENDMENTS

The following is a marked up version of each amended claim in which underlines indicates insertions and strike-throughs indicate deletions.

1. A ~~sustained-release~~tablet composition free of food effect comprising:

(a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and

(b) a functional coating ~~comprising~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of, based on the weight of the coating, from 0 to 30% by weight of polyethylene glycol and from 30 to 80% of a gastroresistant polymer soluble at a pH above 5.5, and the non-polymer component comprises, based on the weight of the coating~~and~~, from 10 to 40% of a hydrophilic silicon dioxide.

2. ~~The~~ A composition according to claim 1, ~~in which~~wherein the gastroresistant polymer is selected from the group consisting ~~in~~ of uncured poly(meth)acrylic acids, cellulose phthalates, ~~and alkylcellulose phtalates.~~alkylcellulose phthalates, an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and combinations thereof.

3. ~~The~~ A composition according to claim 1, ~~in which~~wherein the ~~functional~~ coating ~~further~~ comprises ~~polyethyleneglycol, present in an amount~~ from 5 to 30% by weight polyethylene glycol~~, based on the total weight of the functional coating~~.

4. ~~The~~ A composition according to claim 1, ~~in which~~wherein the ~~functional~~ coating represents from 0.5 to 6% by weight of the core weight.

9. A ~~sustained release~~tablet composition free of food effect comprising:

(a) a core comprising from 20 to 80% by weight of verapamil and 10 to 80% by weight of a gelling agent; and

(b) a ~~functional~~ coating ~~comprising~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of, based on the weight of the coating, from 0 to 30% by weight of polyethylene glycol and from 30 to 80% of ~~a gastroresistant polymer comprised of~~ uncured poly(meth)acrylic acids, and wherein the non-polymer component comprises from 10 to 40% of a hydrophilic silicon dioxide.

10. ~~The~~ A composition according to claim 9, ~~in which~~ wherein the ~~functional~~ coating ~~further~~ comprises ~~polyethyleneglycol, present in an amount~~ from 5 to 30% by weight polyethylene glycol. ~~, based on the total weight of the functional coating.~~

11. A ~~sustained release~~tablet composition free of food effect comprising:

(a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and

(b) a ~~functional~~ coating ~~comprising~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of, based on the weight of the coating, from 5 to 30% by weight of polyethylene glycol and from 30 to 80% of ~~a gastroresistant polymer comprised of uncured poly(meth)acrylic acids,~~an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and the non-polymer component comprises from 10 to 40% of a hydrophilic silicon dioxide ~~and from 5 to 30% by weight of polyethyleneglycol.~~.

15. A ~~process~~ method for alleviating food effect in a pharmaceutical composition, comprising the step of coating a core comprising verapamil with a ~~functional~~ coating ~~comprising~~consisting of a polymer component and a non-polymer

component, wherein the polymer component consists essentially of, based on the weight of the coating, from 0 to 30% by weight polyethylene glycol and from 30 to 80% of a gastroresistant polymer soluble at a pH above 5.5, and the non-polymer component comprises from 10 to 40% of an hydrophilic silicon dioxide.

16. ~~The process of~~A method according to claim 15, ~~in which the composition is as defined in claim 1~~wherein the gastroresistant polymer comprises an anionic copolymer of methacrylic acid and acrylic acid ethyl ester.

17. ~~The process of~~A method according to claim 15, ~~in which the composition is as defined in claim 9~~wherein the coating comprises from 5 to 30% by weight of polyethylene glycol.